K033338

JAN - 8 2004

510(k) Summary

NAME OF SPONSOR:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, Indiana 46581-0988 Est. Reg. No. 1818910
510(K) CONTACT:	Bob Friddle, BSME Consultant, Regulatory Affairs Telephone: (574) 371-4925 Fax: (574) 371-4987
DATE PREPARED:	November 18, 2003
TRADE NAME:	Pinnacle™ Revision System
COMMON NAME:	Acetabular Cup Prosthesis
CLASSIFICATION:	Class II Device per 21 CFR 888.3358: Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis
DEVICE PRODUCT CODE:	87 LPH
SUBSTANTIALLY EQUIVALENT DEVICES:	DePuy Pinnacle™ Acetabular System Summit™ Acetabular System DePuy Duraloc® Cementless Acetabular Cup System DePuy Duraloc® Cementless Acetabular Cup System Marathon™ Cross-Linked Polyethylene Acetabular Cup Liners 36mm Marathon™ +4 Polyethylene Liners Modified DePuy Acetabular System

DEVICE DESCRIPTION:

The Pinnacle™ Revision System is a modular system for resurfacing the acetabulum in total hip arthroplasty. It is a line extension of the DePuy Pinnacle™ Acetabular System. The system consists of two separate units, a shell and a liner. The shell substrate is manufactured from forged or wrought titanium alloy (Ti-6AL-4V). The outer porous-coating (Porocoat®) consists of commercially pure titanium beads metallurgically bonded to the shell substrate. The interior of the shell is designed to mate with a variety of styles of liners that lock into the shell. The liner is manufactured from Ultra-high molecular weight polyethylene (UHMWPE). The liners contain multiple ARDs (anti-rotation devices) that engage mating shell features to prevent rotation within the shell. The ARDs enable variable rotational alignment of Face Changing (+4 / 10°) and Lipped liners for patient appropriate positioning. The acetabular liner articulates with a compatible femoral head of appropriate diameter.

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510(k) Summary (cont.)

The Pinnacle™ Revision System extends the existing Pinnacle™ Acetabular System shell options by providing Multihole, Standard Profile and DPx (Deep Profile) configurations. The Revision DPx Shells provide lateralization of the femoral head. Both Revision Standard Profile and Revision DPx shells provide peripheral screw holes in addition to dome screw holes. The screw holes permit use of compatible titanium alloy screws to provide immediate adjunct fixation, stability and intimate contact with bone. The shells contain an apical threaded hole to attach the shell insertion instrument and grasp the shell during implantation. An optional titanium alloy (Ti-6Al-4V) apical hole plug is available to screw into the threaded apical hole of the shell.

The Pinnacle™ Revision System extends the range of Pinnacle™ Marathon Liners by offering corresponding sizes for 28, 32 and 36mm femoral heads in Neutral, +4, and +4 / 10° degree configurations and a Lipped liner configuration for 28 and 32mm femoral heads.

INTENDED USE AND INDICATIONS:
Total Hip Arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. The Pinnacle Revision System is intended to be used to resurface the Acetabular socket in cemented or cementless total hip arthroplasty.

The Pinnacle™ Revision System is indicated for total hip replacement in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

The Pinnacle™ Revision System Acetabular Cup Shell components are indicated for cementless application.

BASIS OF SUBSTANTIAL EQUIVALENCE:
Based on the same Intended Use, Indications for Use, materials, sterilization processes and similarities of technological and geometric features, DePuy believes that the subject Pinnacle™ Revision System components are substantially equivalent to the previously cleared DePuy predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 8 2004

Ms. Natalie Heck
Manager, Regulatory Affairs
DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K033338
Trade/Device Name: Pinnacle™ Revision System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: LPH
Dated: December 11, 2003
Received: December 12, 2003

Dear Ms. Heck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Pinnacle™ Revision System

Intended Use/Indications for Use

Total Hip Arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. The Pinnacle Revision System is intended to be used to resurface the Acetabular socket in cemented or cementless total hip arthroplasty.

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5. Certain cases of ankylosis.

The Pinnacle™ Revision System Porocoat® porous-coated Acetabular Cup Shell components are indicated for cementless application.

PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhorn

for K033338

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

(510(k) Number) K033338

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)